

Amendment and Response

Page 9 of 13

HANSON et al.

Serial No.: 09/814,252

Filed: 21 March 2001

For: PRIMERS FOR USE IN DETECTING BETA-LACTAMASES

Remarks

The Office Action mailed 08 April 2003 has been received and reviewed. Claims 1, 2, 4, 5, 7-11, 19, 21, 25, 27, 31, 33, 35, 36, 38, 49-57 having been amended, the pending claims are claims 1, 2, 4, 5, 7-11, 17-21, 24-27, 30-38, and 49-57.

Claims 49, 51, 52, and 54 have been amended simply to correct a grammatical error. No new matter has been added as a result of these amendments.

Claims 1, 2, 4, 5, 7-11, 19, 21, 25, 27, 31, 33, 35, 36, 38, 50, 53, 55, and 57 have been amended to recite the "full-length complements" of the claimed primers. This amendment clarifies that the primers of these claims are directed toward their full-length complement and not to complementary fragments or bases thereof. It is respectfully submitted that this would be clearly understood by one of skill in the art upon reading Applicants' specification.

Claim 56 has been amended per the Examiner's suggestion.

Reconsideration and withdrawal of the rejections are respectfully requested

Restriction Requirement

In response to the Restriction Requirement mailed 19 November 2002, Applicants clarify that they elected, with traverse, Group V (claims 11, 56, and 57), drawn to a diagnostic kit for detecting a PSE1, PSE4, or CARB3 family beta lactamase and related primers, not Group IV, which was an inadvertent typographical error.

Applicants continue to request reconsideration and withdrawal or modification of the restriction requirement. At least because the claimed primers are relatively short, it is respectfully submitted that the inventions as claimed can be readily evaluated in one search without placing undue burden on the Examiner.

Applicants also continue to request that Group XIII, drawn to a method for identifying a beta-lactamase in a clinical sample (independent claim 17), and claims including the elected PSE1, PSE4, or CARB3 family beta lactamase and related primers depending therefrom (claims 37 and 38), be examined with Group V. Again, Group XIII, including claims 17, 37, and 38, could be examined with Group V, as these claims recite and/or encompass the primer pair recited in the claims of Group V.

Amendment and Response

Page 10 of 13

HANSON et al.

Serial No.: 09/814,252

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For: PRIMERS FOR USE IN DETECTING BETA-LACTAMASES

Applicants respectfully request reconsideration of the restrictions in this case and submit that the inventions as claimed can be readily evaluated in one search without placing undue burden on the Examiner while a significant burden would be placed on Applicants to prosecute and maintain 13 patents.

Priority

The specification has been amended herein to update the status of application 09/407,818 which has now issued as Patent No. 6,242,223, to which the present application claims priority.

Sequence Rules Compliance

Applicants acknowledge with thanks the Examiner's finding that the sequence listing as originally filed complies with the Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures.

Claim Objections

The Examiner objected to claim 56 as lacking the article "a" in the phrase "beta-lactamase nucleic acid of interest" recited in (a) of the claim. Applicants submit that the amendment to claim 56 made herein overcomes the Examiner's objection. It is requested that the Examiner withdraw this objection.

The 35 U.S.C. §102(b) Rejection

The Examiner rejected claim 11 under 35 U.S.C. §102(b) as being anticipated by Arlet et al. (FEMS Microbiology Letter, 82, 19-26, 1991). Applicants respectfully traverse this rejection.

For a claim to be anticipated under 35 U.S.C. §102(b), each and every element of the claim must be found in a single prior art reference (M.P.E.P. § 2131). Applicants respectfully assert that Arlet et al. fail to teach each and every element of claim 11.

Claim 11 recites a primer selected from the group of:

Amendment and Response

Page 11 of 13

HANSON et al.

Serial No.: 09/814,252

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For: PRIMERS FOR USE IN DETECTING BETA-LACTAMASES

5' - CTC GAT GAT GCG TGC TTC GC - 3' (SEQ ID NO:32);
5' - GCG ACT GTG ATG TAT AAA CG - 3' (SEQ ID NO: 33); and full-length complements thereof.

As indicated by the Examiner at page 6, paragraph 2 of the present Office Action, the sequence OS-2 disclosed by Arlet et al. is only a partial complement of SEQ ID NO:33, as recited in claim 11, and not a full-length complement thereof. It is therefore submitted that Arlet et al. fail to teach each and every element of claim 11, that is SEQ ID NO:32, SEQ ID NO: 33, and full-length complements thereof, as required under 35 U.S.C. §102.

Reconsideration and withdrawal of the rejection is respectfully requested.

The 35 U.S.C. §103(a) Rejection

The Examiner rejected claims 56 and 57 under 35 U.S.C. §103(a) as being unpatentable over Arlet et al. as applied to claim 11 above, and further in view of Fluit et al., (WO 91/08305). Although Applicants do not agree with this rejection, in the interest of expediting prosecution, the claims have been amended pursuant to the Examiner's suggestion, thereby rendering this rejection moot.

To establish a *prima facie* case of obviousness, the cited documents must, *inter alia*, teach or suggest all elements of the claim. Applicants respectfully assert that Arlet et al. in view of Fluit et al. fail to teach or suggest all elements of claims 56 and 57.

Claim 56 recites a diagnostic kit for detecting a PSE1, PSE4, or CARB3 family beta-lactamase which comprises packaging, containing, separately packaged:

- (a) at least one primer pair capable of hybridizing to a beta-lactamase nucleic acid characteristic of the PSE1, PSE4, or CARB3 families of beta-lactamase enzymes;
- (b) a positive and negative control; and
- (c) a protocol for identification of the beta-lactamase nucleic acid characteristic of PSE1, PSE4, or CARB3 families of beta-lactamase enzymes.

Table 2 of Arlet et al. disclose one primer OC-2, used to detect a CARB-3 family beta-lactamase (Arlet et al., page 23). Arlet et al. fail to teach or suggest at least one primer pair, as recited in claim 56, which is capable of hybridizing to a PSE1, PSE4, or CARB3 family beta-lactamase.

Amendment and Response

Page 12 of 13

HANSON et al.

Serial No.: 09/814,252

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The Examiner indicated at page 8, lines 1-4 of the present Office Action, that Arlet et al. teach OS-2 and OC-1 as a primer pair capable of hybridizing to an SHV beta-lactamase, and further indicated at page 8, lines 14-15, that OS-2 and OC-1 are not used to detect a PSE1, PSE4, or CARB3 family beta-lactamase. The Examiner then stated that the phrase "detect a PSE1, PSE4, or CARB3 family beta-lactamase" had not been given patentable weight because it occurs in the preamble of the claim. Although Applicants do not agree with this rejection, in the interest of expediting prosecution, claim 56 has been amended accordingly, thereby rendering this rejection moot.

Claim 57 recites the kit of claim 56 wherein at least one of the primers is selected from the group consisting of SEQ ID NO:32, SEQ ID NO:33, and full-length complements thereof. Applicants respectfully point out to the Examiner that claim 57 does not recite a partial complement of SEQ ID NO:32 or SEQ ID NO:33. As Arlet et al. disclose only a partial complement of SEQ ID NO:33, Applicants submit that Arlet et al., in addition to failing to teach or suggest the kit of claim 56, fail to teach or suggest the kit of claim 57.

Fluit et al. teach a bacteria diagnostic kit (page 8, lines 3-10, for example). However, Fluit et al. do not teach or suggest that which is missing from Arlet et al. Applicants, therefore, submit that claims 56 and 57 are nonobvious over Arlet et al. in view of Fluit et al.

Reconsideration and withdrawal of the rejection is respectfully requested.

Amendment and Response

Page 13 of 13

HANSON et al.

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Summary

It is respectfully submitted that the pending claims 1, 2, 4, 5, 7-11, 17-21, 24-27, 30-38, and 49-57 are in condition for allowance and notification to that effect is respectfully requested.

The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
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PATENT TRADEMARK OFFICE

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that this paper is being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Assistant Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 8th day of July, 2003, at 5:38 PM (Central Time).

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